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STATE OF NEW JERSEY
DEPARTMENT OF LAW AND PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
STATE BOARD OF PHARMACY

FILED

JUN 21 2004

BOARD OF PHARMACY

IN THE MATTER OF THE SUSPENSION OR REVOCATION OF THE LICENSE OF BURT FRIEDMAN, R.P. TO PRACTICE PHARMACY IN THE STATE OF NEW JERSEY	**FINAL DECISION AND ORDER**

This matter was initially opened to the New Jersey State Board of Pharmacy on the Attorney General's filing of an Administrative Complaint on February 9, 2001 against Burt Friedman, R.P. ("respondent") by Paul R. Kenny, Deputy Attorney General. Respondent's answer to the Complaint was filed on May 22, 2001 by Timothy J. Dunn II, Esq., Angelo J. Cifaldi, Esq. and David C. Kane, Esq.

The Administrative Complaint alleged the following: The respondent is a pharmacist licensed in the State of New Jersey and was employed as the Registered Pharmacist-in-Charge at Abel's Pharmacy, Paterson, New Jersey. On or about February 24, 2000, a prescription for patient Ximena Clavijo, was filled at the pharmacy. The prescription was for the chemotherapeutic agent, CCNU*, 190 milligrams, and was to be taken by mouth at bedtime

* CCNU (CeeNU) (Limoustine)

every six weeks. The pharmacy dispensed a supply of CCNU that was forty times greater than the dose that was prescribed. Pursuant to the labeling placed on three vials dispensed by the pharmacy to the patient, Ximena Clavijo ingested a capsule from each of three vials every night for twenty-one consecutive days until she was admitted to Wayne General Hospital on March 17, 2000 with bone marrow suppression and other complications from the overdose. Ms. Clavijo died on April 22, 2000; the cause of death was attributed to sepsis/aplastic anemia due to antineoplastic drug overdose. The Complaint further alleged that, as the Registered Pharmacist in Charge of Abel's Pharmacy, respondent failed to ensure that the medication dispensed conformed with the prescription received by the pharmacy; that he failed to ensure that the medication was properly labeled; that he failed to ensure compliance in filling the prescription with all statutes, rules and regulations covering the practice of pharmacy; in violation of *N.J.A.C.* 13:39-13.18(e)3, 7, and 14 and *N.J.S.A.* 45:1-21(h), that he failed to carry out his responsibility for ensuring the accuracy of the prescription filled for the patient in violation of *N.J.S.A.* 45:1-21(h); that he failed to conduct a prospective drug review for the prescription drug; dispensed an incorrect dosage or duration of drug treatment; and engaged in clinical abuse or misuse in violation of *N.J.S.A.* 45:14-15.1(a)(1), (4), (6) and *N.J.S.A.* 45:1-21(h); that he failed to offer counseling to the patient in violation of *N.J.S.A.* 45:14-

15.2(a) and *N.J.S.A.* 45:1-21(h); that he failed to properly interpret the prescription issued; that he failed to observe the warnings for the use of the drug; that he failed to observe the usual supply of the drug and instead dispensed a supply forty times greater than that prescribed; that he failed to properly consult with the physician issuing the prescription, and, thus, engaged in gross malpractice, gross negligence, or gross incompetence in violation of *N.J.S.A.* 45:1-21(c); and engaged in repeated acts of negligence, malpractice or incompetence in violation of *N.J.S.A.* 45:1-21(d).

Following respondent's filing of an Answer denying the allegations and demanding that the complaint be dismissed, the matter was transmitted to the Office of Administrative Law as a contested case on July 23, 2001. The hearing commenced on December 17, 2002 and continued on May 12, 13, 14, and 15, 2003. By letter dated August 12, 2003, the State withdrew the claim that the alleged conduct violated *N.J.S.A.* 45:1-21(d), repeated acts of negligence, malpractice or incompetence.

The Initial Decision of Administrative Law Judge Robert J. Giordano was issued on March 18, 2004 and received by the Board on March 23, 2004. The respondent requested an extension to file Exceptions to the decision; the Attorney general consented. Exceptions were filed by both parties by May 12, 2004 and Replies to the Exceptions were received and filed with the Board by May 23,

2004. The Board applied for and received an extension for filing a Final Decision until June 22, 2004, given respondent's request for additional time to submit his Exceptions and the State's conflict with a proceeding before another professional board.

The Board considered the Exceptions and replies to the Exceptions of the parties at its regularly scheduled meeting on May 26, 2004. The Board permitted oral argument as to the Exceptions and the replies. At the time of Argument, the Attorney General presented Certifications of DAG Kenny and the Board's Executive Director, Joanne Boyer, which set forth the costs borne by the State for attorney's fees, expert fees and expenses and costs attributed to conducting and recording the administrative proceeding. Over objection of respondent, both certifications were entered into evidence.*

After due consideration of the Administrative Law Judge's decision, transcripts, exhibits and exceptions, replies and arguments of counsel , the Board adopted as its final decision the findings of fact, in total, and the conclusions of law, in part, of the Administrative Law Judge (hereinafter, ALJ). Thus, the Board finds that the respondent failed to ensure that the medication dispensed conformed with the prescription received, in violation

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* The Board's determination as to costs will be discussed infra.

of *N.J.A.C.* 13:39-3.18(e)3, that the respondent failed in his personal responsibility as supervising pharmacist for the accuracy of the filled prescription, in violation of *N.J.A.C.* 13:39-6.4, and that the respondent failed to conduct a prospective drug review, in violation of *N.J.S.A.* 45:14-15.1. The Board adopts the ALJ's conclusion of law that the State failed to establish that the the offer to counsel was not made, in accordance with *N.J.S.A.* 45:14-15.2.

The Board, however, rejects the ALJ's conclusion of law that the conduct of the respondent while negligent and careless, does not rise to the level of gross negligence. Rather, The Board, based on its own expertise, including the expertise of five practicing registered pharmacists, agrees with the testimony of the State's expert witness, and concludes that respondent's conduct rises to the level of a patently substantial departure from accepted standards of care and treatment and, as such, he has engaged in gross negligence, gross malpractice, and gross incompetence, in violation of *N.J.S.A.* 45:1-21(c).

DISCUSSION

The gravamen of this case is whether Burt Friedman has engaged in gross negligence, gross malpractice, or gross incompetence which damaged or endangered the life, health, welfare, safety or property of any person. The Board concurs with the definition set forth in the ALJ's Order, "gross negligence occurs

when there is ... a patently substantial departure from accepted standards of care and treatment." (ALJ's Order, page 43). As ALJ Giordano has explained, a licensee's deviation from the normal standard of care is an act of neglect, but when the conduct goes so far beyond that deviation such that the conduct endangers the life or health of the patient, then that conduct suggests gross negligence. (See ALJ's Order, page 44). The Board of Pharmacy has examined that conduct which consisted of a multitude of actions on the part of respondent, and in his supervision of his non-licensed assistant, and those acts committed in that single dispensing deviate so far from the standard of care, that the Board finds that respondent has engaged in gross negligence, gross malpractice, or gross incompetence. The series of errors engaged in by respondent, that is the constellation of failures to adhere to the most basic duties of a pharmacist in dispensing a powerful chemotherapeutic drug with its inherent dangers, can be nothing other than gross negligence. Respondent utterly failed in his responsibility to use his expertise as a pharmacist to protect the patient, which resulted in endangering her safety and her life.

As ALJ Giordano has determined, Friedman is the registered pharmacist and he is personally responsible for the accuracy of the filled prescription. First, according to ALJ Giordano, the pharmacist must be charged with the responsibility to possess product knowledge. William Vilensky, D.O., the State's

expert, testified that it is within the standard of care for a pharmacist to look up a powerful, chemotherapeutic drug such as CCNU in a standard text and to read the information contained therein before dispensing (1T88:3-9). Respondent followed that standard when he actually turned to the text of "Drugs Facts and Comparisons." Immediately under the name of the medication, there is a prominent black box which contained a clear and unambiguous warning about overdose and directives that a dose of CCNU should not be given more frequently than once every six weeks, and under "Administration and Dosage" the admonition, "... as a single oral dose every six weeks. (See Exhibit S-6). The "Black Box" is a red flag known to every pharmacist. It is basic to pharmacy training that black box warnings must be read, understood and followed prior to dispensing due to the dangers which may be posed to the patient.

Mr. Kowalski, a registered pharmacist who provided expert testimony on behalf of respondent, testified that many drugs have these black boxes, but the Board finds that does not mitigate failure to read that warning before dispensing. Respondent's expert testified that so many black boxes exist because there are problems associated with so many medications. The Board agrees with that assessment and finds that the dangers in dispensing highly toxic medications mandates the careful reading of those warnings. To do otherwise, or worse yet, to not even read the warning, as the ALJ found respondent failed to do, when the

pharmacist has no familiarity with a highly toxic drug, is a gross deviation and a patently substantial departure from the standard of care.

ALJ Giordano concluded that respondent failed to conduct a prospective drug review by failing to ascertain the proper dose and duration of treatment. In the ALJ's words, "a simple review of the references at hand would have disclosed the dangers extant in such overdose." (ALJ Order, page 46). The ALJ goes on, " clearly communicating a concern to the prescribing physician would have been equally important to the proper discharge of his responsibilities." (Ibid.). Friedman, having failed to obtain product knowledge and having failed to correctly identify the symbol "q" to mean "every", misinterpreted the prescription to mean that the 190mg dose should be given every day for six weeks. According to respondent, he called the prescribing doctor only to obtain authorization to dispense a forty day supply rather than a forty-two day supply, and not to clarify the dose. The doctor returned the call and spoke with someone in the pharmacy, and he told that person that a delay in the dispensing for several days was permissible. Had Friedman read the text of "Drug Facts and Comparisons" that specific failure in communication would not have occurred. Rather, if Friedman read the prescription to require a dose equal to 40 times the amount that was explicitly and prominently displayed in the warning box and in the directives as

to dosage and administration, the question to the doctor, as testified to by Dr. Vilensky, should have been "Do you want this given every day for six weeks, or just one time in a six week span?" Even if the physician then insisted that such a lethal dose was to be given anyway, the State's expert testified that a prudent pharmacist would advise the physician that he could not dispense that dose (1T90:1-13). We agree.

ALJ Giordano found there was clear evidence in this case of therapeutic duplication. Dr. Vilensky commented on Friedman's reaction to the notice of "duplicate therapy" provided by the Kin Ray computer. He testified that the notice of duplication should have been recognized "... as a red flag or gong" notifying Friedman that this was an exceedingly large amount of medication for a single order (1T113:22-25, 114:1-4). Respondent's expert has testified that putting it into the computer was a sufficient prospective drug review. The Board finds that latter conclusion to be flawed. Friedman, having failed to obtain product knowledge, and now faced with duplicate therapy warnings, disregarded the repeated warnings, made no attempt to refer back to any text, manufacturer's insert, the "Physician's Desk Reference" or even the pharmacy's own computer generated insert, any and all of which would have alerted him as to the egregious error he was about to make, and rather, continued to order the excessive dose.

Dr. Vilensky, in his testimony, has characterized this dispensing to be the product of reckless indifference, by no means intentional, but conduct that so substantially departs from the standard of care, that it can only be considered gross malpractice (1T117:6-25, 1T118:1-17). Friedman, not being familiar with the drug looked up the medication in the appropriate text, but then failed to read the warnings. These warnings contained in the black box are so important that the black box is taken out the normal format, which calls for the black box to be placed under the indications of the drug, and instead, it is placed directly under the name of the drug (1T76:1-24). That black box contains the critical directive that the drug should not be given more frequently than every six weeks. The product description told how to dispense this drug, and it was to be placed in one vial, not three vials as the respondent did, and explained to the patient that there are different colored pills in it, but this is one dose to be swallowed at bedtime (1T118:1-12). The State's expert has characterized respondent's conduct to be a gross deviation from the standard of care and absolutely irreparable. (1T118:13-17). We agree.

The Board, consistent with the above, adopts all of the findings of fact and conclusions of law of the ALJ, except the Board rejects the last conclusion of law, "that the conduct of the respondent, while negligent and careless, does not give rise to

the level of gross negligence." (ALJ Order, page 46). As ALJ Giordano has articulated, the licensing board and, on appeal, the court, determines how far beyond such deviation the conduct must be to constitute, gross neglect, gross malpractice, or gross incompetence. The Board concludes that respondent has engaged in conduct that is a patently substantial departure from accepted standards of care and treatment, and as such, he has engaged in gross negligence, gross malpractice, or gross incompetence which endangered the life, health and welfare of his patient, in violation of *N.J.S.A.* 45:1-21(c).

Prior to determining the penalty, the Board afforded both respondent and complainant the opportunity to present mitigating and aggravating circumstances, respectively, or make further argument as to the appropriate sanction. Respondent testified before the Board, turned to the family of the deceased and, rather than accepting responsibility for his egregious error, said only that he was sorry "that this happened." However, this error and the excruciating result did not just happen. Even now respondent fails to take personal responsibility for his actions and omissions.

In his closing remarks, respondent's counsel reminded the Board that the respondent is near retirement and that a suspension would be tantamount to a revocation. However, that decision rests totally with the respondent and not this Board. The Board finds

that the appropriate penalty in this case is a substantial suspension of license. The ALJ has determined that a three year active suspension is appropriate. The Board, however, has concluded that the conduct rises to the level of gross negligence thus justifying even more significant discipline. Therefore, the Board has determined to impose a five year suspension of license. The first three years shall be served as an active suspension and shall commence July 1, 2004; the last two years shall be stayed and served as a period of probation. In addition, the Board has determined to impose a civil penalty of $10,000 pursuant to it's statutory authority set forth in *N.J.S.A.* 45:1-25(a).

In the State's exceptions, costs for the use of the State were requested. The State offered and the Board accepted into evidence over respondent's objection, certifications from DAG Paul Kenny and Executive Director Joanne Boyer, both delineating those costs with specificity. The respondent's exceptions addressed this issue, arguing that the ALJ had not imposed costs, that respondent had been afforded no opportunity to cross-examine regarding the reasonableness of the costs given their untimely submission, and finally that the Board should bear the costs given the Board's rejection of the respondent's initial settlement. Following oral argument, the Board granted the respondent an additional ten days to make written submissions as to the whether the Board should impose costs set forth in the certifications.

The Board reviewed the submissions of counsel at the regularly scheduled meeting on June 9, 2004. The Board is aware that the costs in total could not be calculated until the conclusion of the proceedings held at the Office of Administrative Law. The Board is also aware that costs are ordinarily not an issue until liability is found and that professional boards routinely consider costs upon consideration of an Initial Decision of an ALJ. The Board has had the opportunity to review thoroughly the certifications in evidence, as have the parties, and finds that the sums reflected in the certifications appear reasonable, given the magnitude of the case, the amount of time this matter has consumed, the need for expert testimony, and the complexity of the proceeding. The Board is now asked by respondent to assess no costs, lest (1), respondent suffer financial detriment, and (2) the licensed community be deterred from exercising its right to be heard in a contested matter. These issues were raised in respondent's Exceptions, and respondent, having been given additional time to specifically address and be heard on the reasonableness of the certifications and the specific, detailed costs, has raised no objections.

If the Board were to fail to recoup these costs, the licensed community would, in effect, pay the expense of this licensee's decision to proceed in a contested matter. Thus, the

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Board, at its meeting on June 9, 204, determined to assess the full costs of the proceeding as requested by the State.

ACCORDINGLY, IT IS ON THIS 21st DAY OF JUNE, 2004

ORDERED:

1. Respondent's license shall be, commencing July 1, 2004 suspended for five (5) years. The first three (3) years of the suspension shall be active; the last two years shall be served in a probationary status. Respondent shall comply with the directives applicable to disciplined licensees which are attached hereto.

2. Respondent shall pay a civil penalty of $10,000 and costs for the use of the State of $84,832.54, by certified check or money order payable to the Treasurer of the State of New Jersey and forwarded to Joanne Boyer, Executive Director of the Board of Pharmacy at 124 Halsey Street, 6th Floor, Newark, New Jersey, 07101, within 30 days of entry of this Order.

3. Respondent shall surrender to the New Jersey State Board of Pharmacy his license to practice pharmacy in the State of New Jersey by July 1, 2004.

State Board of Pharmacy

By: Edward G. McGinley, RP
Edward G. McGinley, RP
President

DIRECTIVES

1. Pending further order of the Board, respondent shall cease and desist from engaging in the practice of pharmacy including the following: respondent shall not handle, order, inventory, compound, count, fill, refill or dispense any drug; he shall not handle anything requiring a prescription including devices and medications; he shall not handle prescriptions; he shall not advise or consult with patients, and he is prohibited from being present within a prescription filling area of a pharmacy.

2. Respondent shall surrender his wall certificate, renewal license and wallet license immediately to the Board of Pharmacy Office for safe keeping.